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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,129

09/20/2006

Robert Dean Dally

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ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

WILLIS, DOUGLAS M

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

01/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/599,129	Applicant(s) DALLY ET AL.	
	Examiner DOUGLAS M. WILLIS	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 6, 11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 8 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09-20-06</u> | 6) <input type="checkbox"/> Other: _____ |

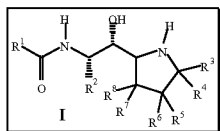
DETAILED ACTION

Status of the Claims / Priority

Claims 2, 8, 11 and 13 are pending in the current application. According to the *Amendments to the Claims*, filed November 20, 2008, claims 2, 8 and 11 were amended, claims 1, 3-7, 9, 10 and 12 were canceled and claim 13 was added. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/US2005/12191, filed April 8, 2005, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/564,538, filed April 22, 2004.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, with traverse, in the reply filed on



November 20, 2008, is acknowledged: a) Group I, claims 2, 8 and 13, where

$R^1 = (C_3-C_7\text{cycloalkyl})_{0-1}(C_1-C_6\text{alkyl})$; $R^2 = \text{-benzyl}$; R^3 and R^4 , taken

together with the carbon to which they are attached, cannot form a C_3-C_6 cycloalkyl ring; R^5 and R^6 , taken together, cannot form $=\text{CHC}(\text{O})(C_1-C_4\text{alkoxy})$; and R^7 and R^8 , taken together, cannot form a bond; and b) substituted pyrrolidine of formula I(a) - p. 160, example 33.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP § 818.03(a).

The requirement is still deemed proper and is therefore made FINAL.

This application contains claim 11, drawn to a nonelected invention, without traverse, in the reply filed on November 20, 2008. A complete reply to the non-final rejection must include

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cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Thus, a second Office action and prosecution on the merits of claims 2, 8 and 13 is contained within.

Status of Claim Rejections - 35 U.S.C. § 112, First Paragraph

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 1 and 9, have been fully considered, but will not be addressed further, since, according to the *Amendments to the Claims*, filed November 20, 2008, claims 1 and 9 have been cancelled by applicant.

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 2 and 8 have been fully considered and are persuasive. Consequently, the rejection of claims 2 and 8, made in the *Non-Final Rejection*, mailed on August 20, 2008, is hereby withdrawn, since, according to the *Amendments to the Claims*, filed November 20, 2008, claims 2 and 8 have been amended to overcome the rejection.

Status of Claim Rejections - 35 U.S.C. § 102

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 1 and 9, have been fully considered, but will not be addressed further, since, according to the *Amendments to the Claims*, filed November 20, 2008, claims 1 and 9 have been cancelled by applicant.

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 2 and 8 have been fully considered and are persuasive. Consequently, the

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rejection of claims 2 and 8, made in the *Non-Final Rejection*, mailed on August 20, 2008, is hereby withdrawn, since, according to the *Amendments to the Claims*, filed November 20, 2008, claims 2 and 8 have been amended to overcome the rejection.

Status of Claim Rejections - 35 U.S.C. § 103

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 1 and 9, have been fully considered, but will not be addressed further, since, according to the *Amendments to the Claims*, filed November 20, 2008, claims 1 and 9 have been cancelled by applicant.

Applicant's arguments, on pages 5-6 of the *Remarks*, filed November 20, 2008, with respect to claims 2 and 8 have been fully considered and are persuasive. Consequently, the rejection of claims 2 and 8, made in the *Non-Final Rejection*, mailed on August 20, 2008, is hereby withdrawn.

New Specification Objection

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

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- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art (including information disclosed under 37 CFR 1.97 and 1.98).
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825).

Applicant is advised to format the specification according to 37 CFR 1.77(b) above.

Revisions should particularly include and/or address: a) bold-type; and b) sections (b-e) and (h).

Appropriate correction is required.

New Specification Objection - Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

With regard particularly to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., *The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics.* Exemplification of a species could be illustrative of members of the class. For processes, the reactions, reagents and process conditions should be stated, generally illustrated by a single example, unless variations are necessary. See MPEP § 608.01(b), Section B.

The abstract of the disclosure is objected to for the following reasons: a) it should be amended to reflect the scope of the *Requirement for Restriction / Election of Species*, as

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discussed herein above and in the *Non-Final Rejection*, mailed on August 20, 2008. Correction is required. See MPEP § 608.01(b).

New Claim Rejections - Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute), so as to prevent the unjustified or improper timewise extension of the *right to exclude* granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claims. {See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)}.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 2, 8 and 13 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 10/599,125. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 6 in the copending application recite identical definitions and limitations for R^1 and R^2 , and further provides definitions and limitations for R^3 , where R^3 is piperidin-2-yl, which provides homologous subject matter with respect to the substituted pyrrolidines and pharmaceutical compositions of formula I(a) in the instant claims.

The MPEP § 2144.09 states that *compounds which are homologs, differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.* {See *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)}.

Similarly, the courts have recognized that *even in the case of homologs, a rejection on the basis of structural relation may be improper, with the critical question to be answered being whether the moieties of the molecules under consideration are considered 'homologous' under some available definition or whether they are sufficiently similar from the standpoint of structural similarity, so that those now claimed would be suggested to chemists from those disclosed and would be expected to have like properties.* (See *Ex parte Burtner and Brown*, 121 USPA 345 (1951).

Moreover, the courts have recognized that *when expectation of similar properties stands unrebutted, it necessarily follows that expectation of similar uses also stands unrebutted, [with] expectation of similar use necessarily implying expectation of substantially equivalent substitute(s).* Furthermore, there is no logical basis for distinguishing patentably between a

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prior art [homologous] compound and a claimed novel compound prima facie obvious therefrom, even where a previously unknown or unobvious use has been found, where that use nevertheless inheres in both compounds and it is the compound per se that is claimed. {See In re Hoch, 57 CCPA 1292, 428 F.2d 1341, 166 USPQ 406 (1970)}.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

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PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**